DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 19,2014

Shantou Wealy Medical Instrument Company Limited
Ms. Charmaine Henderson
Regulatory Consultant
570 Silverado Drive
Lafayette, CA 94549

Re: K141640
Trade/Device Name: Automatically Retractable Safety Syringe with Fixed Needle (1ml, 3ml, 10ml)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: August 25, 2014
Received: August 29, 2014

Dear Ms. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141640

Device Name
Automatically Retractable Safety Syringe with Fixed Needle (1ml, 3ml, 10ml with 30G, 29G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, or 20G)

Indications for Use *(Describe)*
Automatically Retractable Safety Syringe with Fixed Needle (1ml, 3ml, 10ml with 30G, 29G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, or 20G) is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Shantou Wealy Medical Instrument Co. Ltd
Automatically Retractable Safety Syringes with Fixed Needle

Date of Summary Preparation: May 2, 2014

Submitter: Shantou Wealy Medical Instrument Co, Ltd
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Establishment Registration Number: 3005202235

Company Contact: Charmaine Henderson
Regulatory Affairs Consultant
Office: 925.212.5264
Email: crhinlaf@gmail.com

Trade name: Automatically Retractable Safety Syringes with Fixed Needle (1ml, 3ml, 10ml)

Device name (Common Name): Piston syringe

Device Classification: Class II

Product Code: MEG

Regulation Number: 21 CFR 880.5860

Regulation Description: piston syringe

Predicate Device:

Shantou Wealy Medical Instrument Co. Ltd
Automatically Retractable Safety Syringes with Fixed Needle (5 ml)
510(k) K113587
Concurrence date: February 24, 2012

General Device Description:

The Automatically Retractable Safety Syringes with Fixed Needle devices are piston syringes, intended for medical purposes and consist of a calibrated hollow barrel and a movable plunger. The syringe works like a conventional hypodermic syringe except that the contaminated needle is retracted inside the syringe immediately after patient injection. The needle retracting mechanism is activated by a spring action mechanism after injection is completed. The exposed needle remains safely inside the empty syringe barrel for disposal. The Automatically Retractable Safety Syringes with Fixed Needle are sterile, single use, disposable and non-reusable.

Indications for Use:

The Automatically Retractable Safety Syringes with Fixed Needle devices are indicated for use where a safe and reliable method for intramuscular and subcutaneous injection of medication in a patient is desired.

Summary of Technological Characteristics:

The modified Automatically Retractable Safety Syringes with Fixed Needle share the same technological characteristics as its predicate device. The characteristics include the same design, same syringe type, same materials, same principle of operation, same safety features, and same intended use.

Summary of Performance Testing:

The modified Automatically Retractable Safety Syringes with Fixed Needle (1ml, 3ml and 10 ml) devices are substantially equivalent to the predicate device in design, materials, function and intended use. The performance testing of the modified Automatically Retractable Safety Syringes with Fixed Needle devices were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results concluded that the modified Automatically Retractable Safety Syringes with Fixed Needle devices (1ml, 3ml and 10 ml) are substantially equivalent to the predicate device; Automatically Retractable Safety Syringes with Fixed Needle (5ml).

Substantial Equivalence:

Shantou Wealy Medical Instrument Co, Ltd considers the modified Automatically Retractable Safety Syringes with Fixed Needle (1ml, 3ml, and 10ml) product performance to be substantially equivalent to its predicate device, Automatically Retractable Safety Syringes with Fixed Needle (5ml) because there are no changes to the product performance specifications or device functional technology.